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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,746	06/11/2001	Charanjit R. Behl	NPCI-0123A	9881

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EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/882,746	BEHL ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-40* is/are pending in the application.

4a) Of the above claim(s) *33-38 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-32,39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on November 10, 2003 has been entered.

Currently, claims 21-40 are pending in this Application. Claims 33-38 and 40 are withdrawn from consideration.

Applicants' arguments with respect to claims 21-32 and 39 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-32 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,436,950B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. Instant claims are the genus of patented claims therefore the instant claims broadly read on the patented claims above.

Claims 21-32 and 39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62-75 of copending Application No. 10/062021, claims 62-71 of copending Application No. 10/1062020, claims 3-11, 13-17, 24-30, 33-61 of copending Application No. 10/062290 and claims 1-7 of copending Application No. 09/665500. Although the conflicting claims are not identical, they are not patentably distinct from each other because it encompasses same subject matter. Instant claims and the copending claims encompass the composition for treating sexual dysfunction comprising intranasal apomorphine. Instant claims are the genus of patented claims therefore the instant claims broadly read on the patented claims above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 29 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for apomorphine compound as disclosed, does not reasonably provide enablement for the term "chemically modified equivalents" of apomorphine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Claims 29 and 30 embrace any chemically modified equivalents of apomorphine; however, only apomorphine compound is supported by the specification. The guidance given by the specification as to how one would actually practice the invention of utilizing any chemically modified equivalents of apomorphine is minimal. All of the guidance of the working examples are directed to apomorphine compound. The specification teaches how to utilize apomorphine compound in a subject. However, there are no working examples, prophetic or otherwise in the specification to enable all the

chemically modified equivalents of apomorphine. Given the extremely complex nature of the invention, which involves a nasally administered pharmaceutical formulation for treating sexual dysfunction comprising any chemically modified equivalents of apomorphine, the breadth of the claims which encompass all chemically modified equivalents of apomorphine, the complete lack of support from the specification regarding how to interpret the data generated by their formulation toward understanding all chemically modified equivalents of apomorphine for the treatment of sexual dysfunction, complete lack of working examples of all chemically modified equivalents of apomorphine, the uncertainty of whether the current state of the art regarding the use of such formulations would be stable without any chemical precipitation and a degredation and treat sexual dysfunction. It would take undue, unpredictable experimentation to practice applicants' invention to utilize any chemically modified equivalents of apomorphine for treating sexual dysfunction. Therefore, the nasally administered pharmaceutical composition comprising **chemically modified equivalents** of apomorphine for the treatment of sexual dysfunction in a subject is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. The term "chemically modified equivalent" in claims 29 and 30 renders the claim indefinite since it is not clear what are the "chemically modified equivalent" without specific structures or examples of "chemically modified equivalent" of apomorphine. The guidance given by the specification as to what the "chemically modified equivalent" of apomorphine utilized in order to formulate the claimed pharmaceutical composition is not defined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-30 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Merkus (WO 94/22445).

Merkus teaches a pharmaceutical composition comprising including 1 and 2mg of intranasal aqueous formulation of apomorphine. (page 9, lines 4-34, page 10 Examples). Merkus et al. teaches that the nasal pharmaceutical composition comprising apomorphine appear to result in a surprisingly high bioavilability and superior stability of apomorphine. (page 7, lines 6-16).
Applicants' recitation in claims 21of an intended use of treating sexual dysfunction in a mammal, and the apomorphine compound to produce a therapeutic result in the time

periods does not represent a patentable limitation since such fails to impart any physical limitation to the composition and it is inherent property of the same composition claimed by the Applicants. Merkus teaches same active agent, same dosage amounts (as disclosed in Applicants' examples), to a same subject (patient) as set forth by Applicants' claims, therefore any property or therapeutic onset resulted from the composition would be inherent upon the administration of the same composition taught by the prior art. Again, it is noted that intended use does not impart patentable weight to a product. (MPEP 2111.03).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Merkus (WO 94/22445) as applied to claims 21-30 and 39 above, and further in view of Kaul (1960).

Merkus applied as before and additional teaching as follows:

Merkus teaches that the apomorphine composition can be formulated with many other excipients known from the pharmaceutical literature including buffers, and agents to adjust the pH. (page 8, line 35 through page 9, line 2).

Merkus do not teach the pH 3.0-3.5 of the composition set forth in claims 31 and 32.

Kaul teach that the aqueous solution of apomorphine at a pH 1-3 remained stable for a long time (at least six months). (abstract, page 785 left-hand column, lines 9-12).

It would have been obvious to one of ordinary skill in the art to modify the pH of apomorphine nasal composition taught by Merkus to pH 1-3 because aqueous apomorphine composition is stable for a long time when it is formulated in a pH of 1-3 as taught by Kaul and because apomorphine composition is compatable and can be

added with angets to adjust the pH as taught by Merkus. One would have been motivated to make such modification in order to achieve a stable aqueous apomorphine composition for a long time (at least six months). Absent any evidence to contrary, there would have been a reasonable expectation of successfully formulating aqueous apomorphine composition of Merkus in pH range of 1-3 to achieve expected benefit of long lasting stable aqueous apomorphine composition for at least six months.
For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
December 12, 2003

12/11/03